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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In re the Application of | **Janina Baranowski-Kortylewicz, et al.** |
| Application No. | 10/671,376 |
| Attorney Docket No. | 0685-UNMC.63184 |
| Filing Date: | September 25, 2003 |
| For: | CANCER SPECIFIC RADIOLABELED CONJUGATES REGULATED BY THE CELL CYCLE FOR THE TREATMENT AND DIAGNOSIS OF CANCER |
| Examiner: | Not Yet Assigned |
| Group Art Unit: | 1632 |

**CERTIFICATE OF MAILING UNDER 37 C.F.R § 1.8(a)**

I hereby certify that this Correspondence is being deposited on June 8, 2004 with the United States Postal Service as first-class mail in an envelope properly addressed to COMMISSIONER FOR PATENTS, P.O. Box 1450, Alexandria, VA 22313-1450.

June 8, 2004
Date of Certificate

Patrick J. Hagan
Patrick J. Hagan

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97**

In compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, Applicants are submitting herewith a Form PTO-1449 and a copy of the references listed thereon. This Information Disclosure Statement is being filed prior to the mailing of a first Official Action on the merits. Accordingly, no fee is required.

In the opinion of the undersigned, the references submitted herewith are the most pertinent of which the undersigned is aware. However, no representation is made or intended that more pertinent references do not exist.

This submission is not an admission that the references listed on the attached Form PTO-1449 constitute prior art against the claims of this application.

The Examiner is respectfully requested to confirm receipt and consideration of the cited references by initialing and returning a copy of the attached Form PTO-1449 in accordance with MPEP §609.

Early and favorable consideration of this application is respectfully requested.

Respectfully submitted,

DANN, DORFMAN, HERRELL & SKILLMAN
A Professional Corporation
Attorneys for Applicant(s)

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Patrick J. Hagan
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Enclosures - Form PTO-1449
Copies of references listed on PTO - 1449

| INFORMATION DISCLOSURE STATEMENT | *Complete if known* | |
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| | Examiner Name: | Not Yet Assigned |
| SHEET 1 OF 2 | Attorney Docket Number: | 0685-UNMC.63184 |



## UNITED STATES PATENT DOCUMENTS

| EXAMINER'S INITIALS | CITE NO. | PATENT NUMBER | ISSUE DATE MM-DD-YYYY | FIRST NAMED INVENTOR |
|---|---|---|---|---|
| | A1 | 5,096,694 | 03/17/1992 | Quivy et al. |
| | A2 | 5,468,853 | 11/21/1993 | Baranowska-Kortylewicz |

## FOREIGN PATENT DOCUMENTS

| EXAMINER'S INITIALS | CITE NO. | DOCUMENT NUMBER | COUNTRY OR REGION | DATE OF PUBLICATION MM-DD-YYYY | FIRST NAMED INVENTOR OR APPLICANT |
|---|---|---|---|---|---|
| | B1 | WO 90/03799 | WO | 04-19-1990 | Centocor, Inc. |

## OTHER PRIOR ART - NON-PATENT DOCUMENTS

| EXAMINER'S INITIALS | CITE NO. | Include name of the author (in Capital Letters), title of the article (when appropriate), title of the item(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published |
|---|---|---|
| | C1 | BONASERA, T.A. et al. "Preclinical Evaluation of Fluorine-18-Labeled Androgen Receptor Ligands in Baboons"; Journal of Nuclear Medicine, **37(6)**: 1009-1015 (1996) |
| | C2 | CHOE, Y.S. et al. "Synthesis of 11$\beta$-[$^{18}$F]Fluro-5$\alpha$-dihydrotestosterone and 11$\beta$-[$^{18}$F]Fluoro-19-nor-5$\alpha$-dihydrotestosterone: Preparation via Halofluorination-Reduction, Receptor Binding, and Tissue Distribution"; Journal of Medicinal Chemistry, **38(5)**: 816-825 (1995) |
| | C3 | DOWNER, J.B. et al. "Comparison of animal models for the evaluation of radiolabeled androgens"; Nuclear Medicine and Biology, **28(6)**: 613-626 (2001) |
| | C4 | HOYTE, R.M. et al. "7$\alpha$-Methyl-17$\alpha$-(E-2'-[$^{125}$I]iodovinyl)-19-nortestosterone: a new radioligand for the detection of androgen receptor"; Steroids, **58(1)**: 13-23 (1993) |
| | C5 | LABAREE, D.C. et al. "7$\alpha$-Iodine-125-Iodo-5$\alpha$-Dihydrotestosterone: A Radiolabeled Ligand for the Androgen Receptor"; Journal of Nuclear Medicine, **38(3)**: 402-409 (1997) |
| | C6 | LARA, P.N. et al. "Treatment Options in Androgen-Independent Prostate Cancer"; Cancer Investigation, **17(2)**: 137-144 (1999) |
| | C7 | LIU, A. et al. "Fluorine-18-Labeled Androgens: Radiochemical Synthesis and Tissue Distribution Studies on Six Fluorine-Substituted Androgens, Potential Imaging Agents for Prostatic Cancer"; Journal of Nuclear Medicine, **33(5)**: 724-734 (1992) |
| | C8 | SALMAN, M. et al. "A Potential Radioiodinated Ligand for Androgen Receptor: 7$\alpha$-Methyl-17$\alpha$-(2'-(*E*)-iodovinyl)-19-nortestosterone"; Journal of Medicinal Chemistry, **34(3)**: 1019-1024 (1991) |

| **EXAMINER'S SIGNATURE** | | **DATE CONSIDERED** | |
|---|---|---|---|

**EXAMINER**: Initial if reference considered, whether or not citation is in conformance with MPEP §609. Draw a line through citation if citation not in conformance and reference not considered. Include a copy of this form with next communication to applicant.

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| | Examiner Name: | Not Yet Assigned |
| SHEET 2 OF 2 | Attorney Docket Number: | 0685-UNMC.63184 |



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|---|---|---|
| | C9 | VAN DEN BOS, J.C., et al. "New Iodinated Progestins as Potential Ligands for Progesterone Receptor Imaging in Breast Cancer. Part 1: Synthesis and *in Vitro* Pharmacological Characterization"; Nuclear Medicine & Biology, **25(8)**: 781-789 (1998) |
| | C10 | WARTERS, R.L. et al. "Radionuclide Toxicity in Cultured Mammalian Cells: Elucidation of the Primary Site of Radiation Damage"; Current Topics in Radiation Research Quarterly, **12**: 389-407 (1997) |
| | C11 | MAKRIGIORGOS, G.M. et al. "Radiotoxicity of 5-[$^{123}$I]Iodo-2′-deoxyuridine in V79 Cells: A Comparison with 5-[$^{125}$I]Iodo-2′-deoxyuridine"; Radiation Research, **118**: 532 (1989) |
| | C12 | BARANOWSKA-KORTYLEWICZ, J. et al. "5-[$^{123}$I]Iodo-2′-Deoxyuridine in the Radiotherapy of an Early Ascites Tumor Model"; Int. J. Radiat. Oncol. Biol. Phys., **21**: 1541-1551 (1991) |
| | C13 | KYRIAKOS, R.J. et al. "The Fate of Antibodies Bound to the Surface of Tumor Cells *in Vitro*"; Cancer Research, **52**: 835-842 (1992) |
| | C14 | BRYAN, R.M. et al. "Androgen Receptors in Breast Cancer"; Cancer, **54**: 2436-2440 (1984) |
| | C15 | LEA, O.A. et al. "Improved Measurement of Androgen Receptors in Human Breast Cancer"; Cancer Research, **49**: 7162-7167 (1989) |
| | C16 | SOREIDE, J.A. et al. "Androgen receptors in operable breast cancer: relation to other steroid hormone receptors, correlations to prognostic factors and predictive value for effect of adjuvant tamoxifen treatment"; European Journal of Surgical Oncology, **18**: 112-118 (1992) |
| | C17 | POULIN, R. et al. "Androgens inhibit basal and estrogen-induced cell proliferation in the ZR-75-1 human breast cancer cell line"; Breast Cancer Research and Treatment, **12**: 213-225 (1988) |
| | C18 | INGLE, J.N. et al. "Combination Hormonal Therapy With Tamoxifen Plus Fluoxymesterone Versus Tamoxifen Alone in Postmenopausal Women With Metastatic Breast Cancer"; Cancer, **67**: 886-891 (1991) |
| | C19 | MARIANI, G. et al. "Tumor Targeting Potential and Metabolism of 5-[$^{125}$I]Iodo-2′-Deoxyuridine Injected Intratumorally in Patients with Breast Cancer"; Ann N Y Acad. Sci., **698**: 204-211 (1993) |

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